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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/506,469	10/15/2004	Yasuo Suzuki	2004-1390A	8950

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EXAMINER	
KHARE, DEVESH	
ART UNIT	**PAPER NUMBER**
1623	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/23/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/506,469	SUZUKI ET AL.	
	Examiner	Art Unit	
	Devesh Khare	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 November 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11,12,14-17,19 and 20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11,12,14-17,19 and 20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/06/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Applicant's amendments and remarks filed on 11/06/2006 are acknowledged. Claims 11-12, 14-17 and 19-20 have been amended. Claims 13 and 18 have been cancelled.

The IDS dated 11/06/2006 has been entered.

The objection and rejections under 35 U.S.C. 112, second paragraph and 35 U.S.C. 102(b) of the Office Action dated 05/05/2006 have been overcome by the applicant's amendments.

Claims 11-12, 14-17 and 19-20 are currently pending in this application.

35 U.S.C. 103(a) rejection

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The amended claims 11-12, 14-17 and 19-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Suzuki (Prog. Lipid Res. Vol. 33, No.4, pp 429-457, 1994) in view of Masuda et al. (FEBS Letters 464, 71-74, 1999) of record.

It is noted that claim 20 is rejected because claim 20 depends on claims 11,15 and 16.

Suzuki teaches that influenza A, B and C viruses specifically recognize and bind to a sugar chain containing a sialic acid (N-acetylneuraminic acid or NeuAc) in common of the gangliosides (see Introduction pages 430-431). Suzuki discloses that the virus bound most effectively to lacto-series gangliosides such as Neu5Acα2,3Gal-GlcNAc-ceramide type I and type II sugar chains (page 440, lines 1-7). Suzuki discloses the I-Active ganglioside which shows high binding to influenza A virus (page 445, last

structure in Table 1 and Table 5 on page 450) which renders the sialo-sugar molecule represented by formula I, II and III prima facie obvious. Furthermore, ganglioside such as GM1b, GD1a and GT1b having a sugar chain Neu5Acα2,3Gal-GalNAc-hex-ceramide shows moderate binding to influenza A and B viruses (Table 1, page 444). Suzuki also discloses binding reactivity of synthetic ganglioside analogs to human influenza A virus wherein terminal sialic acid is linked to penultimate galactose in thioglycoside linkage (page 447, Table 3 (g)). Suzuki discloses that these biologically active gangliosides may be used as anti-influenza drug or vaccine (page 431, line 6). The I-Active ganglioside (page 445) of the prior art differ from the applicant's that Suzuki does not explicitly teaches a ganglioside wherein terminal sialic acid is linked to penultimate galactose in 2-6 linkage however Suzuki discloses that human influenza B virus binds very strongly to 2-3 and 2-6 linkages, almost equally (page 451, 2nd para.).

Masuda et al. teach the binding reactivity of human influenza A viruses to four types of sialoglycolipids wherein the terminal sialyl linkage is varied (page 71, 2nd col. end of 2nd para.).Masuda et al. disclose that human influenza A virus recognized the Neu5Ac2-6Gal linkage more strongly than Neu5Ac2-3Gal (page 72, 2nd col. lines 1-9 and for glycolipid structures see Table 1 on page 73, first two structures).

Therefore, one of ordinary skill in the art would have found the applicants claimed sialo-sugar molecules represented by the formulae I, II and III wherein the terminal sialic acid is linked to penultimate galactose in 2-6 and 2-3 linkages in combination with the sugar chain Gal-GlcNAc or Gal-GalNAc and an antiviral agent thereof, to have been obvious at the time the invention was made having the above cited references before

him. Since Suzuki teaches the branched sialo-sugar molecules such as I-Active ganglioside wherein terminal sialic acid is linked to penultimate galactose in 2-3 linkage in combination with the sugar chain Gal-GlcNAc shows high binding to influenza A virus or the sugar chain Gal-GalNAc shows moderate binding to influenza viruses and Masuda et al. teach that human influenza A virus recognizes the Neu5Ac2-6Gal and Neu5Ac2-3Gal linkages, one skilled in the art would have a reasonable expectation for success in combining the teachings of these references to accomplish a sialo-sugar molecule having both Neu5Ac2-6Gal and Neu5Ac2-3Gal linkages in combination with the sugar chains such as Gal-GlcNAc or Gal-GalNAc.

The motivation is provided by Suzuki reference which discloses that these biologically active gangliosides can be used as anti-influenza drug and vaccine (page 431, line 6).

Rejection Maintained

Rejection of amended claims 11-12, 14-17 and 19-20 under 35 U.S.C. 103(a) is maintained for the reasons of record.

Applicant's arguments traversing the rejection of claims 11-12, 14-17 and 19-20 under 35 U.S.C. 103(a) have been fully considered but they are not persuasive.

Response to Arguments

Applicant argue, "Yasuo Suzuki and do not suggest the specific branched structure of the present invention and superior effect thereof."

Suzuki discloses that the virus bound most effectively to lacto-series gangliosides such as Neu5Acα2,3Gal-GlcNAc-ceramide type I and type II sugar chains (page 440, lines 1-7). Suzuki does not explicitly teaches a ganglioside wherein terminal sialic acid

is linked to penultimate galactose in 2-6 linkage however Suzuki discloses that human influenza B virus binds very strongly to 2-3 and 2-6 linkages, almost equally (page 451, 2nd para.). The deficiency of the Suzuki reference is overcome by the Masuda reference which discloses that human influenza A virus recognized the Neu5Ac2-6Gal linkage more strongly than Neu5Ac2-3Gal (page 72, 2nd col. lines 1-9 and for glycolipid structures see Table 1 on page 73, first two structures).

Therefore, one of ordinary skill would reasonably expect success in combining the teachings of Suzuki and Masuda to accomplish gangliosides having the structure Neu5Acα2,6Gal-GlcNAc-ceramide because the human influenza A virus recognized the Neu5Ac2-6Gal linkage more strongly than Neu5Ac2-3Gal linkage.

2. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office Action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07 (a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Devesh Khare whose telephone number is (571)272-0653. The examiner can normally be reached on Monday to Friday from 8:00 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anna Jiang, Supervisory Patent Examiner, Art Unit 1623 can be reached at

(571)272-0627. The official fax phone numbers for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Devesh Khare, Ph.D.,J.D.
Art Unit 1623
February 19, 2007

2/20/07
SHAOJIA ANNA JIANG, PH.D.
SUPERVISORY PATENT EXAMINER